DETAILED ACTION

This Office Action is substitute for the previous Office Action mailed on 10/16/08.

Applicant's request for reconsideration of the finality of the rejection of the last Office action mailed in 3/20/08 is persuasive and, therefore, the finality of that action is withdrawn.

Claims 16-24 and 38-39 are present for examination.

Claims 1-15 and 25-37 are cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-24, 38-39 are rejected under 35 U.S.C. 103(a) as obvious over Shockey et al. (US 4,994,033) in view of Sogard et al. (US 5,447,497).

Shockey discloses a process for treating tissue at a treatment site within a body lumen, comprising: providing an elongate flexible catheter 12 having a flexible treatment sheath 22 mounted to a distal end region of the catheter and a dilatation balloon 30 within the flexible treatment sheath, wherein the flexible treatment sheath is formed of a elastic material;

intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a treatment site (col. 3, lines 55-66); supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath (through the holes 28) to the surrounding tissue, and maintain the treatment sheath expanded into the contact (col. 3, line 55-col. 4, line 8); and

while maintaining the treatment sheath in the substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue (col. 4, lines 8-29).

Shockey does not disclose the dilation balloon 30 is formed of a substantially inelastic materials.

Sogard discloses a similarly device comprising an elongate flexible catheter 20 having a flexible treatment sheath (outer sheath) 26 mounted to a distal end region of the catheter and a dilatation balloon (inner balloon) 28 within the flexible treatment sheath 26, wherein the flexible treatment sheath 26 is formed of an elastic member, such as high-compliant balloon are made from soft or flexible polymeric materials (col. 2, lines 28-40, col. 8, lines 30-31); and the dilatation/inner balloon 28 is non-compliant balloon are made from inelastic materials such as rigid or stiff polymeric materials (col. 2, lines 43-52, col. 8, lines 49-50).

As noted that Applicant acknowledge that the inelastic materials such as PET, polypropylene (see page 2 of Pre-Appeal Brief filed 7/28/08) are similar to materials that Sogard discussed in col. 2, lines 43-52, col. 8, lines 49-50.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Shockey with a dilatation balloon made of an inelastic material, as taught by Sogard, in order to dilate and prevent the rupture of balloon since the small increase in diameter when the balloon inflated to its expanded diameter

Regarding claim 19, a guide wire 18 with a distal end thereof outside of the body, inserting the proximal end of the guide wire lumen running through the catheter, and advancing the catheter distally relative to the guide wire.

Regarding claims 20-21, the supplying of the treatment fluid comprises causing the treatment fluid to perfuse through the pores 28 in the treatment sheath.

Regarding claims 22-24, the dilatation balloon 30 radially enlargeable by supplying a dilatation fluid to a dilatation chamber formed by the balloon and the catheter, wherein the contraction of the dilatation balloon comprise withdrawing the dilatation fluid from the dilatation chamber to substantially evacuate the dilatation balloon (col. 4, lines10-30); allowing the treatment sheath to radially contract comprise withdrawing the treatment fluid from the compartment through the pores 28; allowing a flow of body fluids through the catheter past the treatment site (col. 4, lines 15-23).

Regarding claim 38, the treatment sheath 22 is formed of a biocompatible elastomeric material such as a thermoplastic elastomer (col. 3, lines 12-16. Furthermore, it is well-known in the balloon art to made of materials in claim 38.

Regarding claim 39, Shockey in view of Sogard fail to disclose that the biocompatible elastomeric material has a modulus of electricity in range of 2,000 to 80,000 psi; the sheath has a thickness in the range of 0.5-5 mils. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the values list in claim 39, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 16-24, 38-39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
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